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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,226	05/08/2001	Jeffry G. Weers	0073.00	4017

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EXAMINER	
WELLS, LAUREN Q	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/851,226	WEERS ET AL.	
	Examin r	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42 and 44-52* is/are pending in the application.

4a) Of the above claim(s) *33-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32 and 44-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-42 and 44-52 are pending. Claims 33-42 are withdrawn from consideration, as they are directed to non-elected subject matter.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-32 and 44-52, drawn to particulate phospholipid compositions and methods of using them, classified in class 424, subclass 502.

II. Claims 33-42, drawn to a method of making particulate phospholipid compositions, classified in class 554, subclass 79.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method can be used to make particulate polyanhydride compositions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Michael Rafa on April 11, 2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-32 and 44-52. Affirmation of this election must be made by applicant in replying to this Office action. Claims 33-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not identify the post office address of each inventor. A post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The post office address should include the ZIP Code designation. The post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6-15, 17-18, 20-22, 27-30, 32, and 44-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 1-5, 7-23, 25, 27, 28-30, 34-37, 41-45 of copending Application No. 09/568818. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed toward particulate compositions comprising phospholipid and polyvalent cation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-14, 43 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) It is not clear if claim 43 is missing or if the claims were numbered incorrectly.

(ii) Claims 10-14 and 49 are vague and indefinite, as it is not clear if the claims lack antecedent basis, or if the term "surfactant" is referring to the phospholipid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-32 and 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanes et al. (5,855,913) in view of Materne et al. (GB 2065659) and in view of ~~Weers et al. (6,309,623).~~ Edwards et al (6,254,854).

Hanes et al. disclose a particulate composition for drug delivery to the pulmonary system comprising biodegradable particles incorporating a therapeutic agent and a surfactant, wherein the particles have a tap density less than 0.4g/cm3 and a mean diameter between 5um and 30um effective to yield an aerodynamic diameter of 1um-3um. The particles are disclosed as further comprising a biodegradable polymer, a polyester, an excipient, or a fatty acid. Albuterol and parathyroid hormone-related peptide are disclosed as therapeutic agents. Dipalmitoyl phosphatidylcholine is disclosed as the preferred surfactant. Polyglycolic acid, polylactic acid, polyethylene glycol, and polyvinyl alcohols are disclosed as biodegradable polymers. Gelatin, trehalose and dextran are disclosed as other materials that can comprise the polymeric particles. The particles incorporating a surfactant and a therapeutic agent can be administered alone or in any appropriate pharmaceutical carrier and can be co-delivered with larger carrier particles. Methods of administering the composition are disclosed. The reference lacks divalent cations and porous particles. See Col. 3, lines 560Col. 4, line 15; Col. 4, line 60-Col. 5, line 47-Col. 6, line 51; Col. 7, line 48-Col. 11, line 14; Col. 19, line 30-Col. 20, line 65.

Materne et al. disclose calcium phosphatidylcholine chloride and pharmaceutical preparations thereof. The pharmaceutical preparations are disclosed as able to be ground to the desired particle size to form a powder or granular product. See abstract; Pg. 1, Col. 2, line 80-Pg. 2, Col. 1, line 13.

Edwards et al. disclose porous particles for deep lung delivery. Porous particles made of a biodegradable material and having a mass density less than 0.4g/cm3 and a mean diameter of between 100nm and 15um, are disclosed. See Col. 3, line 250Col. 4, line 14.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the calcium phosphatidylcholine of Materne for the phosphatidylcholine of Hanes et al. because Materne discloses that calcium phosphatidylcholine is processed more readily than pure phosphatidylcholine and that powder or granular products containing calcium phosphatidylcholine have increased stability.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the particles of Hanes et al. as porous because Edwards et al. teach that porous particles a) permit deep lung delivery of relatively large diameter therapeutic aerosols; b) are highly suitable for controlled release inhalation applications; c) more successfully avoid phagocytic engulfment and clearance from the lungs, and; d) aerosolize more efficiently.

Claims 1-32 and 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weers et al. (6,309,632) in view of Materne et al.

Weers et al. disclose a respiratory dispersion for the pulmonary delivery of one or more bioactive agents comprising a suspension medium having dispersed therein a plurality of perforated and/or hollow microstructures having a mean aerodynamic diameter of less than 5 um. The perforated microstructures comprise a surfactant, wherein the surfactant is a phospholipid, nonionic detergent, nonionic block phospholipid, ionic surfactant, and combinations thereof. Dipalmitoylphosphatidycholine is disclosed as the phospholipid. Other surfactants, co-solvents, stabilizers, buffers, viscosity modulators, solubility modulates, and salts are disclosed as addition

components for use in the composition. Albuterol and others are disclosed as active agents. The reference lacks divalent cations. See Col. 4, line 5-Col. 7, line 51; Col. 16, line 28-Col. 20, line 20; Col. 24, line 56-Col. 25, line 5.

Materne et al. is applied as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the calcium phosphatidylcholine of Materne for the phosphatidylcholine of Weers et al. because Materne discloses that calcium phosphatidylcholine is processed more readily than pure phosphatidylcholine and that powder or granular products containing calcium phosphatidylcholine have increased stability.

Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the data on pages 22-40 of the specification have been considered but not found persuasive because the data merely demonstrate the effectiveness of the instant composition in being delivered to the pulmonary system. This is seen to be an expected result based on the cited prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
April 12, 2002